BIOMET
SPORTS MEDICINE

MAR 18 2013

510(k) Summary

Preparation Date: October 31, 2012

Applicant/Sponsor: Biomet Sports Medicine

Contact Person: Elizabeth Wray / Global RA Project Manager
(574)-267-6673

Proprietary Name: JuggerKnotless™ Soft Anchors

Common Name: Soft Tissue Fixation Device

Classification Name: Fastener, fixation, nondegradable, soft tissue
(21CFR §888.3040) MBI
Staple, fixation, bone (21CFR §888.3030) JDR

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

K080088	Biomet Sports Medicine Anchor Devices and ZipLoop™ Constructs
K110145	JuggerKnot™ Soft Anchors

Device Description:
The JuggerKnotless™ Soft Anchors consist of a coreless sleeve structure and a knotless construct incorporating ZipLoop™ Technology. The anchors are intended for use in soft tissue fixation by bunching against bone when deployed.

Intended Use / Indications for Use:
The JuggerKnotless™ Soft Anchors are indicated for soft tissue reattachment procedures in the shoulder, foot/ankle, elbow, knee, hand/wrist, and hip. Specific indications are as follows:

Shoulder
Acromio-clavicular Separation, Anterior Shoulder Instability Repair, Bankart lesion repair, Biceps tenodesis, Capsule Repair or Capsulolabral Reconstruction, Deltoid Repair, Rotator Cuff Repair, S.L.A.P Lesion Repairs

Foot and Ankle
Achilles Tendon Repair/Reconstruction, Hallux Valgus Reconstruction, Lateral/Medial Stabilization Repairs/Reconstruction, Midfoot/Forefoot Reconstruction/Repairs

Elbow
Biceps Tendon Reattachment, Biceps Tendon Reconstruction, Lateral/Medial Repairs, Lateral Epicondylitis Repair (Tennis Elbow Repair), Ulnar & Radial Collateral Ligament Reconstruction

Mailing Address:
P.O. Box 587
Warsaw, IN 46581-0587
Toll Free: 800.348.9500
Office: 574.267.6639
Main Fax: 574.267.8137
www.biomet.com

Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

Knee
Iliotibial Band Tenodesis, Joint Capsule Closure, Lateral/Medial Collateral Ligament Repair, Patellar Ligament Repair, Patellar Tendon Repair, Patellar Realignment/Repair, Posterior Oblique Ligament Repair, VMO Advancement

Hand and Wrist
Collateral Ligament Repair (Gamekeeper's Thumb), Scapholunate Ligament Reconstruction, Tendon Transfers in Phalanx, Volar Plate Reconstruction

Hip
Labral

Summary of Technologies:
The technological characteristics (materials, design, sizing and indications) of the JuggerKnotless™ Soft Anchors are similar or identical to the predicate devices or other previously cleared devices.

Non-Clinical Testing:
Non-clinical laboratory testing was performed to verify the fixation strength of the JuggerKnotless™ Soft Anchors in mechanical pullout testing as compared to the predicate devices for specific indications for use. The efficacy of the JuggerKnotless™ Soft Anchors was compared to that of the Biomet Sports Medicine 2.4mm PEEK Hitch Anchor. The test results indicate that the Biomet Sports Medicine JuggerKnotless™ Soft Anchors provide equivalent fixation strength to the predicate devices and would be functional within their intended use.

Clinical Testing:
None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 18, 2013

Biomet Sports Medicine
% Ms. Elizabeth Wray
Senior Regulatory Affairs Specialist
P.O. Box 587
Warsaw, Indiana 46581

Re: K123485
Trade/Device Name: JuggerKnotless™ Soft Anchors
Regulation Number: 21 CFR 888.3040, 21 CFR 888.3030
Regulation Name: Smooth or threaded metallic bone fixation fastener, Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MBI, JDR
Dated: February 25, 2013
Received: February 26, 2013

Dear Ms. Wray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123485

Device Name: JuggerKnotless™ Soft Anchors

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Hip
Labral

Prescription Use ___X___ AND/OR Over-The-Counter Use ___NO___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopaedic Devices